



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,243	11/07/2001	Kevin Kelly Covey	1023-015US01	8259
28863	7590	12/07/2005	EXAMINER	
SHUMAKER & SIEFFERT, P. A.			MANUEL, GEORGE C	
8425 SEASONS PARKWAY				
SUITE 105			ART UNIT	
ST. PAUL, MN 55125			PAPER NUMBER	
			3762	

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Tata

Office Action Summary	Application No.	Applicant(s)	
	10/008,243	COVEY ET AL.	
	Examiner	Art Unit	
	George Manuel	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,7-20 and 22-59 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3,7-20 and 22-59 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 8, 9, 11 and 13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Freeman et al '157.

Freeman teaches the connector can be exposed without exposing the electrode, and the electrode can be pre-connected to a medical device without the risk of contaminating the electrode or drying out its conductive adhesive layer. Thus, the electrode can be connected to the medical device before an emergency arises, and the step of connecting the electrode to the device, and its associated delay, can be eliminated from the electrode application procedure in an emergency situation such as when defibrillation is required. See col. 2, lines 22-30.

Claim 35 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nova et al '885.

Electrode 22 shows a human figure oriented on a defibrillation electrode at an angle. See Fig.3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 7, 10, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al '157.

The examiner is interpreting connector 24 to comprise an anchor that fastens an electrode 18 to a defibrillator. A handle comprises tab 40. One of ordinary skill in the art would have found it obvious to provide a hermetic seal 36 because Freeman et al teach the seal 36 is a heat seal and heat seals are known for use in hermetic sealing and hermetic seals are well known to keep patient contact elements sterile. Further, the examiner is interpreting the pulling of tabs 40 away from each other inherently moves the tabs away from the anchor, connector 24.

Regarding claim 7, one of ordinary skill in the art would have found it obvious to form connector 24 to be substantially cylindrical because the connector is intended to be inserted in a defibrillator housing and cylindrical shapes are easy to grasp.

Regarding claim 10, the examiner is interpreting region 32 to comprise a notch proximate to the anchor comprising connector 24.

Regarding claim 14, the examiner is interpreting adhesive strip 30 to comprise a lip.

Claims 15, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al '157 in view of Janae et al '051.

Freeman et al fail to show instructions illustrating opening of the pouch, electrode placement, or pulling in a defined direction.

Janae et al teach using illustrations and instructions 44 on an electrode pouch. One of ordinary skill in the art would have found it obvious to use the illustrations and instruction teaching of Janae et al for illustrating opening of the pouch, electrode placement, or pulling in a defined direction on the pouch disclosed in Freeman et al because both pouches are intended to house defibrillation electrodes which rely on correct placement and rapid deployment.

Claims 17-20, 22, 28-31, 34, 53, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al '157 in view of Bost et al '245 .

Freeman et al show all of the claimed features except for a ring-shaped handle.

Bost et al disclose a ring-shaped handle comprising tab 24 to pull a bag apart.

See Fig. 3.

One of ordinary skill in the art would have found it obvious to form a ring-shaped handle as taught by Bost et al in lieu of tab 40 in Freeman et al because the tab 24 of Bost et al is designed for gripping with a finger and a thumb for a similar purpose as a finger and a thumb grip tab 40 in Freeman et al.

Claims 26-28, 33, 35-38, 40-43, 45, 46, 53 and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walters et al '640 in view of Bost et al '245 and further in view of Bishay et al '598.

Walters et al show all of the claimed features except for a ring-shaped handle.

Bost et al disclose a ring-shaped handle comprising tab 24 to pull a bag apart.
See Fig. 3.

One of ordinary skill in the art would have found it obvious to form a ring-shaped handle as taught by Bost et al to secure electrodes in package 10 of Walters et al because the teaching of Bost et al applies to assisting in the opening of packages and the package 10 of Walters et al requires prompt and efficient opening in emergencies.

Walters et al in view of Bost et al as discussed above, show all of the claimed features except for instructive pictures on the electrodes to illustrate placement of the electrodes on the patient.

Bishay et al teach using images on electrodes to assist an operator in determining placement of electrodes on a patient. One of ordinary skill in the art would have found it an obvious modification of the electrode imaging to image the packaging material instead of, or in addition to, the electrode imaging because the imaging is disclosed as being visible through the packaging material in Fig. 1. Fig. 1 shows a human figure oriented on the defibrillation electrode at an angle (with respect to the figure) so that when the defibrillation electrode is applied to a patient with the head of

Art Unit: 3762

the patient and the head of the human figure in the same direction, the defibrillation electrode will be oriented at the angle.

One of ordinary skill in the art would have found it obvious to combine the teaching of Bishay et al with the electrodes of Walters et al for illustrating placement of the electrodes because the teaching of Bishay et al applies to defibrillation electrodes which are the same type of electrodes disclosed in Walters et al and because time is critical for fast electrode placement and a visual display on the electrode minimizes the time needed for an operator to place the electrodes on a patient.

Regarding claims 45, 49 and 50, one of ordinary skill in the art would have found it obvious to use distinct coloring because Bishay et al teach a combination of color usage and bolding may be employed to enhance the readability of the images. It follows that this inherently contrasts the images to the liner.

Claims 23, 24, 25, 32, 35, 39, 41, 43, 44, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walters et al '640 in view of Bost et al '245 and in view of Bishay et al '598 and further in view of Nova et al '070.

Claims 28, 35, 41, 43 and 53 are rejected as being unpatentable over Walters et al in view of Bost et al and further in view of Bishay et al as stated above.

One of ordinary skill in the art would have further found it obvious to provide instructions for opening the package disclosed in Walters et al in view of the teaching in Nova et al that an additional visual instruction may be displayed for electrode package opening action.

The teaching of Nova et al applies to a similar package of defibrillator electrodes and therefore applies to the package arrangement of Walters et al in view of Bost et al in view of Bishay et al.

Claims 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walters et al '640 in view of Bishay et al '598.

Walters et al show all of the claimed features except for instructive pictures on the electrodes to illustrate placement of the electrodes on the patient.

Bishay et al teach using images on electrodes to assist an operator in determining placement of electrodes on a patient. Fig. 1 clearly shows a first human figure oriented in a first direction (denoted by direction arrow 38') relative to the right defibrillation electrode, and a second human figure oriented in a second direction (denoted by direction arrow 38) relative to the left defibrillation electrode. One of ordinary skill in the art would have found it an obvious modification of the electrode imaging to image the packaging material instead of, or in addition to, the electrode imaging because the imaging is disclosed as being visible through the packaging material in Fig. 1. Fig. 1 shows a human figure oriented on the defibrillation electrode at an angle (with respect to the figure) so that when the defibrillation electrode is applied to a patient with the head of the patient and the head of the human figure in the same direction, the defibrillation electrode will be oriented at the angle.

One of ordinary skill in the art would have found it obvious to combine the teaching of Bishay et al with the electrodes of Walters et al for illustrating placement of


the electrodes because the teaching of Bishay et al applies to defibrillation electrodes which are the same type of electrodes disclosed in Walters et al and because time is critical for fast electrode placement and a visual display on the electrode minimizes the time needed for an operator to place the electrodes on a patient.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.


George Manuel
Primary Examiner
Art Unit: 3762